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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112701-780	2286

29157 7590 07/14/2008
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
07/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/088,766	KUSLYS ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 2, 5, and 11-12 are cancelled. Claims 1, 3, 4, 6-10 and 13-20 are under consideration in this office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 16, 2008 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102 is maintained.

It is noted that WO 95/17102 provides priority for US Patent 5,916, 621; however US Patent 5,916,621 will act as the English language version of WO 95/17102.

The claims are drawn to a composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-

glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Claim 10 is drawn to method of producing an infant formula, the method comprising the-step-of blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan, and homogenizing the blended mixture. Claim 20 is drawn to a method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan.

The rejection is on the grounds that Yonekubo et al., teach highly digestible nutritive compositions for infant use comprising natural milk proteins, amino acids as the protein source, nutrients such as lipids (fats) and carbohydrates. Yonekubo et al., teach the whey powder obtained from the milk serum portion that is left after casein has been removed. Therefore casein is removed from the whey to produce sweet whey. Yonekubo et al., teach the amino acids used in the compositions are free amino acids such as histidine and tryptophan. However Yonekubo et al., do not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. Georgi et al, teach that it is important to use whey powder/proteins that do not contain glycomacropeptide (GMP).

Therefore it would have been prima facie obvious at the time of applicants' invention to modify the sweet whey composition for an infant formula, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide has been removed as taught by Georgi et al. Moreover, one of ordinary skill in the art would have a reasonable expectation of success since well known commercially available methods were used to formulate the infant formulas and method of production and administration which had been routinely observed in the prior art to provide baby formulas by adding GMP free whey proteins which are dominant in baby milk foods.

Response to Arguments

4. Applicant's arguments have been fully considered but they are not persuasive. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102 is maintained for reasons of record.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels is advantageous to infants and that by removing the GMP from whey, one of ordinary skill in the art can provide formula with significantly reduced the threonine levels which is beneficial to infants. Furthermore, no more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Therefore applicants' arguments are not persuasive.

Again, applicants' argue that the Yonekubo et al., reference teaches away from the claimed invention because Yonekubo et al., teach an example where threonine is added to the composition. Contrary to applicants' arguments, one of ordinary skill in the art would have been motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels achieved by removing the GMP from whey, is advantageous to infants. It is noted that the need for reduced threonine levels does not equate to compositions not having any threonine content as Applicants argue. The teachings of Yonekubo et al., where threonine is added does not discount the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

The prior art teaches the need for reduced levels, which Yonekubo et al., in view of Georgi et al., teach. Furthermore, Quero et al., [Journal of Pediatric Gastroenterolgy and Nutrition. 1997. Vol. 24(4): 491], teach the incidence of hyperthreoninemia is reduced by feeding infants whey predominant formula without GMP. Quero et al., clearly states that threonine concentrations are still found in GMP-free formula and in breast milk. Therefore applicants' argument that the addition of threonine would negate the effects of reduced threonine when protein is not persuasive, since infant formula and breast milk clearly contains threonine.

It is also the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, rather the references teach the need to reduce the threonine content, not eliminate the threonine content.

Therefore, contrary to applicants' arguments, one of ordinary skill in the art would have been motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach advantageously providing infant formula without high threonine levels is achieved by removing the GMP from whey.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Therefore a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that one of ordinary skill in the art knew that high threonine levels in infants causes hyperthreoninemia; and Georgi et al., teach milk baby foods have the disadvantage of having a high threonine content therefore Georgi et al., teach the need for milk compositions with a reduced threonine content. Accordingly, applicants' arguments are not persuasive, since the instant claims do not become patentable simply because the prior art products have been described as somewhat inferior to other products for the same use.

Applicants' argue that the references fail to disclose or suggest every element of the claims, in that the references do not the milk protein comprising 5% or more of tryptophan is not taught by Yonekubo et al.

Applicants' argue that the references do not teach a milk protein having 5% or more of tryptophan. Contrary to applicants' statements, Yonekubo et al., clearly teach the inclusion of a milk protein comprising 5% or more of tryptophan. Yonekubo et al.,

teach compositions comprising natural milk proteins, whey powder, nutrients and carbohydrates. Furthermore, neither Applicants claims nor specification state what specific milk protein is comprised in the instantly claimed composition, which would allow for an appropriate comparison. Yonekubo et al., teach milk proteins having 5% or more of tryptophan. Yonekubo et al., teach whey powder as a milk protein serum protein and casein. Therefore Yonekubo et al., teach a milk protein having 5% or more of tryptophan that does not include the amino acids added in free form. Applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645